

October 10, 2002

Dockets Management Branch (HFA-305) Food and Drug Administration Department of Health and Human Services 5630 Fishers Lane Room 1061 Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

This Citizen's Petition is submitted by the undersigned on behalf of Banner Pharmacaps, Inc. under the authority of 21 CFR §10.30, 21 CFR §314.93, and Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act. The petitioner is requesting that the Food and Drug Administration permit the filing of an Abbreviated New Drug Application for a proposed drug product that has the same active ingredient, is of the same strength, and is expected to have the same therapeutic effect as that of a Reference Listed Drug in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, but differs in dosage form.

A. Action Requested

By this petition, the Commissioner of the Food and Drug Administration is being requested to declare that:

- (1) A new drug application for Naproxen Sodium, 220 mg (equivalent to 200 mg Naproxen) soft gelatin capsules is suitable for submission as an Abbreviated New Drug Application (ANDA), pursuant to 21 CFR §314.94;
- (2) The Reference Listed Drug (RLD) on which the contents of this petition is based is Bayer Corporation's Aleve® (Naproxen Sodium, 220 mg) tablets;
- (3) Therefore, a request is being made to change the dosage form from tablet to soft gelatin capsule.

0Q P.0473





At this time, the undersigned is also requesting a waiver of the requirement to conduct pediatric studies in accordance with 21 CFR §314.55(c)(2). The basis for this request is that:

- (1) The effectiveness of the proposed drug product can be extrapolated from adequate and well-controlled studies in adult and pediatric populations;
- (2) The dosing and safety data for relevant age groups is well-defined;
- (3) The innovator product has a long history of use in ages 12-17 as an OTC drug (first approved as an oral tablet January 11, 1994);
- (4) The drug product is not labeled with dosage recommendations in children less than 12 years old.

B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act allows for the submission of an Abbreviated New Drug Application for a proposed new drug product that differs in dosage form from that of the Reference Listed Drug on which it is based, provided that the Commissioner of Food and Drugs has approved a petition, filed by or on behalf of the applicant, requesting a declaration that an application to market a drug product with such change is suitable for an ANDA submission.

The Commissioner of Food and Drugs has previously approved ANDA suitability petitions of this nature, in particular, those in which the petitioners have sought to change the dosage form in order to make an alternate dosage form available for those who have difficulty swallowing tablets or simply prefer the alternative.

In support of this petition, the following information is being provided:

- (1) The proposed drug product is a soft gelatin capsule with the same active ingredient, the same strength, and the same route of administration as that of the RLD, Aleve® (Naproxen Sodium, 220 mg) tablets. A copy of the most recent Orange Book listing of "Approved Drug Products with Therapeutic Equivalence Evaluations" is provided. (Attachment 1)
- (2) The proposed drug product will be labeled with the same conditions of use as the RLD for consumers 12 years of age and older, and is expected to have the same therapeutic effect when used as indicated in the labeling. A copy of the RLD labeling is provided. (Attachment 2)

(3) Labeling for the proposed drug product and the RLD will differ with respect to dosage form, inactive ingredients, and manufacturer/distributor identification and contact information. A draft of the proposed drug product labeling is provided. (Attachment 3)

C. Environmental Impact

The applicant claims a categorical exclusion under 21 CFR §25.31.

D. Economic Impact

Information will be provided upon request of the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted by:

Donna Lu

Donna Lee, R.Ph.

Director of Regulatory Affairs and Project Management

Phone: (800) 447-1140 ext. 3312

(3) Attachments

ATTACHMENT 1

Active Ingredient Search Results from "OTC" table for query on "naproxen."

Appl No	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
020204	Yes	NAPROXEN SODIUM	Tablet; Oral	EQ 200MG BASE	ALEVE	BAYER
075168	No	NAPROXEN SODIUM	Tablet; Oral	EQ 200MG BASE	NAPROXEN SODIUM	DR REDDYS LABS INC
074646	No	NAPROXEN SODIUM	Tablet; Oral	EQ 200MG BASE	NAPROXEN SODIUM	INVAMED
074635	No	NAPROXEN SODIUM	Tablet; Oral	EQ 200MG BASE	NAPROXEN SODIUM	LEINER
074661	No	NAPROXEN SODIUM	Tablet; Oral	1	NAPROXEN SODIUM	PERRIGO
074789	No	NAPROXEN SODIUM	Tablet; Oral	1	NAPROXEN SODIUM	PVT FORM
021076		PSEUDOEPHEDRINE HYDROCHLORIDE	Tablet, Extended Release; Oral		ALEVE COLD AND SINUS	BAYER

Thank you for searching the Electronic Orange Book

Return to Electronic Orange Book Home Page

Search results from the "OTC" table for query on "020204."

Active Ingredient: NAPROXEN SODIUM

Dosage Form;Route: Tablet; Oral Proprietary Name: ALEVE

Applicant: BAYER

Strength: EQ 200MG BASE

Application Number: 020204
Product Number: 002

Approval Date: JAN 11, 1994

Reference Listed Drug Yes RX/OTC/DISCN: OTC

Patent and Exclusivity Info for this product: Click Here

Thank you for searching the Electronic Orange Book!

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ATTACHMENT 2

PDR for Nonprescription Drugs® and Dietary Supplements™ entry for

ALEVE® (Bayer Consumer)

All Day Strong naproxen sodium tablets, 220 mg Pain reliever/fever reducer

ALEVE® Caplets * , Gelcaps ** , or Tablets Naproxen Sodium Tablets, USP

Active Ingredient:

Purpose:

(in each tablet/caplet/gelcap)

Naproxen sodium 220 mg (naproxen 200 mg) Pain reliever/Fever reducer

Uses: Temporarily relieves minor aches and pains due to:

- common cold
- headache
- toothache
- muscular aches
- backache
- menstrual cramps
- minor pain of arthritis

temporarily reduces fever

Warnings: Allergy Alert: Naproxen sodium may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you s take naproxen sodium or other pain relievers/fever reducers. Naproxen sodium may cause stomach bleed

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have had serious side effects from any pain reliever/fever reducer

Ask a doctor or pharmacist before use if you are

- taking any other product that contains naproxen sodium or any other pain reliever/fever reducer
- taking other drugs on a regular basis
- under a doctor's care for any continuing condition

Stop use and ask a doctor if:

- an allergic reaction occurs. Seek medical help right away.
- any new or unexpected symptoms occur
- symptoms continue or worsen
- you have difficulty swallowing or it feels like the pill is stuck in your throat
- you develop heartburn
- stomach pain occurs with use of this product or if even mild symptoms persist
- pain worsens or lasts for more than 10 days
- fever lasts for more than 3 days
- painful area is red or swollen

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor be it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Cente right away.

Directions:

- do not take more than directed
- drink a full glass of water with each dose

ALEVE® Caplets

Over age 65	1 caplet every 12 hours. Do not exceed 1 caplet in 12 hours, unless directed by a doctor.
	take 1 caplet every 8 to 12 hours. For the first dose you may take 2 caplets within the first hour. Do not take more than 2 caplets in any 8 to 12 hours, or 3 caplets in a 24 hour period. The smallest effective dose should be used.
under 12 years	• ask a doctor

ALEVE® Gelcaps

Over age 65	1 gelcap every 12 hours. Do not exceed 1 gelcap in 12 hours, unless directed by a doctor.
	take 1 gelcap every 8 to 12 hours. For the first dose you may take 2 gelcaps within the first hour. Do not take more than 2 gelcaps in any 8 to 12 hours, or 3 gelcaps in a 24 hour period. The smallest effective dose should be used.
under 12 years	• ask a doctor

ALEVE® Tablets

Over age 65	1 tablet every 12 hours. Do not exceed 1 tablet in 12 hours, unless directed by a doctor.	
-	take 1 tablet every 8 to 12 hours. For the first dose you may take 2 tablets within the first hour. Do not take more than 2 tablets in any 8 to 12 hours, or 3 tablets in a 24 hour period. The smallest effective dose should be used.	
under 12 years	• ask a doctor	

Other Information:

- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat 40°C (104°F)

ALEVE® Caplets

• each caplet contains: sodium 20 mg

ALEVE® Gelcaps

• each gelcap contains: sodium 20 mg

ALEVE® Tablets

• each tablet contains: sodium 20 mg

Inactive Ingredients:

ALEVE® Caplets: Magnesium stearate, microcrystalline cellulose, opadry YS-1-4215, povidone, talc.

ALEVE® Gelcaps: D&C yellow #10 lake, disodium EDTA, edible ink, FD&C blue #1, FD&C yellow # lake, gelatin, glycerin, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid, talc, titanium dioxide, triacetin.

ALEVE® Tablets Magnesium stearate, microcrystalline cellulose, opadry YS-1-4215, povidone, talc.

How Supplied:

ALEVE® Caplets in boxes of 8, 24, 50, 100, 150, 200.

ALEVE® Gelcaps in boxes of 20, 40, 80.

ALEVE® Tablets in boxes of 24, 50, 100, 150.

^{*} capsule-shaped tablet(s)

^{**} gelatin coated capsule-shaped tablet(s)

Questions or comments? call 1-800-395-0689 or www.aleve.com

Do not use if carton i	is open or if foil se	al imprinted with	ı "Safety SQUEASI	E ${\mathbb R}$ " on bottle	opening is miss
or broken.	_				

Distributed by

Bayer Corporation

PO Box 1910

Morristown, NJ 07962-1910 USA

B-R LLC

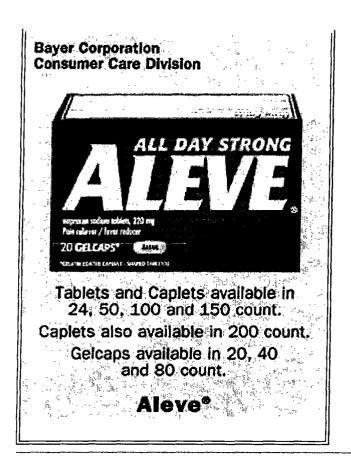
Read Consumer

Leaflet Before Use

PRODUCT PHOTO(S):

NOTE: These photos can be used only for identification by shape, color, and imprint. They do not depict actual *or relative* size.

The product samples shown here have been supplied by the manufacturer and reproduced in full color by as a quick-reference identification aid. While every effort has been made to assure accurate reproduction, please remember that any visual identification should be considered preliminary. In cases of poisoning or suspected overdosage, the drug's identity should be verified by chemical analysis.



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ATTACHMENT 3

NAPROXEN SODIUM Soft Gelatin Capsules

Active ingredient (in each softgel)

Naproxen Sodium 220 mg (Naproxen 200 mg)

Purpose

Pain reliever/Fever Reducer

headache

Uses

■ Temporarily relieves minor aches and pains due to: ■ common cold

toothache muscular aches

■ backache
■ menstrual cramps

minor pain of arthritis

Temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction which may include: ■ hives

■ facial swelling ■ asthma (wheezing) ■ shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take naproxen sodium or other pain relievers/fever reducers. Naproxen sodium may cause stomach bleeding.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.

Ask a doctor before use if you have had serious side effects from any pain reliever/fever reducer.

Ask a doctor or pharmacist before use if you are:

- taking any other product that contains naproxen sodium or any other pain reliever/fever reducer
- taking other drugs on a regular basis
- under a doctor's care for any continuing condition

Stop use and ask a doctor if:

- any allergic reaction occurs. Seek medical help right away
- any new or unexpected symptoms occur
- symptoms continue or worsen
- you have difficulty swallowing or it feels like the softgel is stuck in your throat
- you develop heartburn
- stomach pain occurs with use of this product or if even mild symptoms persist
- pain worsens or lasts for more than 10 days
- fever lasts for more than 3 days
- painful area is red or swollen

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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Directions

- Do not take more than directed■ Drink a full glass of water with each dose
- Age 65 and older: 1 softgel every 12 hours. Do not exceed 1 softgel in 12 hours, unless directed by a doctor.
- 12 –65 years of age: 1 softgel every 8 to 12 hours. For the first dose you may take 2 softgels within the first hour. Do not take more than 2 softgels in a 8 to 12 hour, or 3 softgels in a 24 hour period.
- Under 12 years of age: Ask a doctor.

Other information

- Each softgel contains: sodium 20 mg
- Store between 20-25°C (68-77°F)
- Avoid high humidity and excessive heat [40°C (104°F)]
- See side panel for lot number and expiration date.
- Do not use if carton or blister unit is open or torn.

Inactive ingredients

To be determined

Questions or comments?

To be determined

Distributed by To be determined

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Food and Drug Administration Dockets Management Branch (HFA-305) Department of Heaith and Human Services HIGH POINT, NORTH CAROLINA 27261-2210 P O Box 2210, 4125 PREMIER DRIVE BANNER PHARMACAPS





